

approved facilities must meet the requirements specified in this subpart for the following activities: Training technicians to perform the tests; conducting spirometry tests using equipment and procedures that meet required specifications; collecting the respiratory assessment form; transmitting data to NIOSH; and communicating with miners as required for scheduling, testing, and notification of results. Facilities seeking approval may apply to NIOSH using the Spirometry Facility Certification Document (Form CDC/NIOSH (M)2.14), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>.

(b) *Spirometry quality assurance.* A spirometry quality assurance program must be in place to minimize the rate of invalid test results. This program must include all of the following components:

(1) *Instrument calibration checks.* Testing personnel must fully comply with the 2005 ATS/ERS Standardisation of Spirometry guidelines for instrument calibration check procedures, pp. 322–323, including Table 3 (incorporated by reference, see § 37.97). Calibration check procedures must include daily (day of testing) leak and volume accuracy checks and linearity checks according to the frequency established by the 2005 ATS/ERS guidelines. Instrument calibration check records must be maintained by the facility and available for inspection.

(2) *Automated maneuver and test session quality checks.* The spirometer software must automatically perform quality assurance checks on expiratory maneuvers during each spirometry testing session. Messages must alert the technician to maneuver acceptability errors and test session non-repeatability. Each spirometry test session must have the goal of obtaining 3 acceptable with 2 repeatable forced expiratory maneuvers, as defined by the 2005 ATS/ERS Standardisation of Spirometry, p. 325 (incorporated by reference, see § 37.97).

(3) *Ongoing monitoring of test quality.* Facilities must submit spirometry results to NIOSH within 14 calendar days of testing as specified in § 37.95(d) to permit NIOSH to monitor test quality

and provide a report to the miner. NIOSH may provide feedback to the appropriate technician(s) along with suggestions for improvement.

(4) *Quality assurance audits.* NIOSH may periodically conduct audits to review examinations submitted by approved facilities and assess the quality of spirometry provided. Such audits may include a review of all spirometry examination data obtained during a specified time period or review of spirometry test data collected over time on selected miners.

(c) *Noncompliance.* If NIOSH determines that a facility is not compliant with the policies and procedures specified in this subpart, or determines as the result of a quality assurance audit specified in this section that a facility is not performing spirometry examinations of adequate quality, the facility will be notified of the deficiency. The facility must promptly make appropriate arrangements for the deficiency to be rectified.

(d) *Revocation of approval.* If a facility fails to rectify deficiencies within 60 days of notification, NIOSH approval of the facility may be revoked. An approval which has been revoked may be reinstated at the discretion of NIOSH after it receives satisfactory assurances and evidence that all deficiencies have been corrected and that effective controls have been instituted by the facility to prevent a recurrence.

(e) *Maintenance of records.* In conducting medical examinations pursuant to this part, physicians and radiographic facilities must maintain the results and analyses of these examinations (including any hard copies or digital files containing individual data, interpretations, classifications, and images) in a manner consistent with applicable statutes and regulations governing the treatment of individually identifiable health information, including, as applicable, the HIPAA Privacy and Security Rules (45 CFR part 160 and 45 CFR part 164, subparts A, C, and E).

§ 37.94 Respiratory assessment form.

As part of the spirometry examination and concurrent with it, personnel at the facility must complete a Respiratory Assessment form (Form CDC/

NIOSH (M)2.13), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, for the miner.

§ 37.95 Specifications for performing spirometry examinations.

(a) *Persons administering the spirometry examination.* Each person administering spirometry examinations must successfully complete a NIOSH-approved spirometry training course and maintain a valid certificate by periodically completing NIOSH-approved spirometry refresher training courses, identified on the NIOSH Web site at <http://www.cdc.gov/niosh/>. A copy of the certificate of completion from a NIOSH-approved spirometry training or refresher course, with validation dates printed on the document, must be available for inspection. NIOSH will assign each person administering spirometry examinations a unique identification number, which must be entered into the spirometry system computer whenever instrument quality assurance or miner testing is done or on the Spirometry Results form (Form CDC/NIOSH (M)2.17), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>.

(b) *Spirometer specifications.* Spirometry testing equipment must meet the 2005 ATS/ERS Standardisation of Spirometry specifications for spirometer accuracy and precision and real-time display size and content, pp. 331–333, including Table 2 on p. 322 and Table 6 on p. 332 (incorporated by reference, see § 37.97). Facilities must make available for inspection written verification from a third-party testing laboratory (not the manufacturer or distributor) that the model of spirometer being used has successfully passed its validation checks as required by the Standardization of Spirometry; 1994 Update protocol, Appendix B pp. 1126–1134, including Table C1 (incorporated by reference, see § 37.97). Facilities may request such documentation from spirometer manufacturers. For each forced expiratory maneuver submitted for a miner under this part, the spirometry data file must retain a

record of the parameters defined in the 2005 ATS/ERS Standardisation of Spirometry, p. 335 including Table 8 (incorporated by reference, see § 37.97). Spirometers that provide electronic transfer of spirometry data results files must use the format, content, and data structure specified by the 2005 ATS/ERS Standardisation of Spirometry, p. 335, or a procedure for data transfer that is approved by NIOSH.

(c) *Spirometry examination procedures.* Administration of spirometry examinations must include the following:

(1) *Pre-test checklist.* A short Spirometry Pre-Test Checklist (Form CDC/NIOSH (M) 2.15), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, must be administered prior to each spirometry examination to identify possible contraindications to testing, or factors that might affect results.

(2) *Respiratory assessment.* A standardized Respiratory Assessment form (Form CDC/NIOSH (M)2.13), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, must be completed at the initial spirometry examination and repeated at each spirometry examination.

(3) *Collection of anthropometric and demographic information.* The miner's standing height must be measured in stocking feet using a stadiometer (or equivalent device) each time the miner has a spirometry test. The miner's weight must also be measured (in stocking feet). The miner's birth date, race, and ethnicity must also be recorded. These data will be entered into the spirometry system computer and transmitted with the spirometry data file. For facilities with spirometers that do not permit electronic transfer of data files as specified in § 37.96(d), the Spirometry Results form (Form CDC/NIOSH (M) 2.17), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, will be completed for each miner tested, and will report the numerical results of the highest and second highest results for the FVC and FEV1 and the highest PEF from at least three maximal, acceptable expiratory maneuvers